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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/721,553 | 11/25/2003 | Surinder K. Batra | UNMC.63121.1 | 6633 |

110 7590 10/25/2005

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| EXAMINER | |
|---|---|
| GODDARD, LAURA B | |
| **ART UNIT** | **PAPER NUMBER** |
| 1642 | |

DATE MAILED: 10/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/721,553 | BATRA ET AL. | |
| | Examiner | Art Unit | |
| | Laura B. Goddard, Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *28-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 28-36 are pending and currently under prosecution.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 28-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of laboratory designations only to identify a particular protein or protein fragment such as PD2 renders the claims indefinite because different laboratories may use the same laboratory designation to define completely distinct proteins or protein fragments. For example, Sato et al (American Society of Plant Biologists, 1997, Abstract # 90) use the name PD2 to describe "a distant homolog of trans-Golgi (TGN) membrane protein. Immunoblotting and immunocytochemistry showed that PD2 is localized to chloroplast envelope but not nucleus," indicating a plant protein. Amendment of the claims are to include the **SEQ ID number** which unambiguously defines a given protein or protein fragment.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 28-33 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,932,442 (see sequence search, issued patent database, result 1).

It is noted for examination purposes that Applicant discloses the protein sequence for human PD2 as SEQ ID NO:2 (p. 5, lines 8-10).

The claims are drawn to an antibody specific for a human PD2 protein that is 531 amino acids in length and comprises an amino terminal helix-loop-helix domain and a centrally localized nuclear transport signal and nucleotide binding site (claim 28), wherein the antibody is monoclonal or polyclonal (claims 29 or 30), a method for detecting human PD2 protein comprising contacting a sample with said antibody to form an immune complex and detecting the immune complex (claim 31), wherein the antibody is linked to a detectable label (claim 32), and wherein the detectable label is selected from a radioactive, fluorescent, and enzymatic label (claim 33).

US Patent 5,932,442 teaches the human regulatory molecule (HRM), SEQ ID NO:9 with a 100% amino acid sequence match to SEQ ID NO:2 of the PD2 human

protein disclosed by the Applicant, hence SEQ ID NO:9 comprises the domain, signal, and site encompassed by SEQ ID NO:2. The reference teaches SEQ ID NO:9 is 531 amino acids in length (col. 15, lines 14-34; Table 1). US Patent 5,932,442 teaches polyclonal and monoclonal antibodies specific for the HRM (particularly in col. 4, lines 65-67; col. 34, lines 38-49; col. 35, lines 6-14 and 29-55).

US Patent 5,932,442 teaches that methods of detecting HRM using either polyclonal or monoclonal antibodies specific for the protein are well known in the art and include ELISA, radioimmunoassay, and fluorescence activated cell sorting (col. 31, lines 56-67 to col. 32, lines 1-2), wherein these methods include forming immune complexes with the HRM and antibody wherein the antibody is detectably labeled with an enzymatic label (ELISA), radioactive label (radioimmunoassay), or fluorescent label (fluorescence activated cell sorting).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,932,442 in view of Sigma Immuno Chemicals 1993 Catalog.

It is noted that textural instructions not given patentable weight because a piece of paper is only relevant to the claimed invention if it is functionally tied to the structure

of the invention, for example, demarcations on a measuring cup or slide rule. The instructions included on the piece of paper are viewed as a recitation of intended use and therefore are not given weight in comparing the claim with the prior art. Claim 34 reads on optionally instructional material for a kit for detecting human PD2 protein.

The claims are drawn to a kit for detecting human PD2 protein comprising an antibody specific for PD2 and optionally instructional material (claim 34), wherein said antibody is linked to a detectable label (claim 35), wherein said detectable label is selected from fluorescent, biological, and enzymatic (claim 36).

US Patent 5,932,442 teaches antibodies as set forth above.

Sigma teaches commercially available kits for monoclonal or polyclonal antibodies conjugated to various labels including enzymes (p. 150-152), fluorescent (153-154), and biological (p. 156). For example, Sigma sells a kit for a monoclonal antibody Human IgA1 (p. 158, product number F61016) that is conjugated to the fluorescent label FITC.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the antibody specific for PD2 taught by US Patent 5,932,442 for the IgA1 antibody in the kit taught by Sigma because antibody-label conjugates are well-known in the art, conventionally used, and commercially sold. One would have been motivated to substitute the antibody taught by US Patent 5,932,442 for the antibody taught by Sigma in order to have an antibody that specifically binds PD2 and can be detected, hence the kit would detect the PD2 protein specifically.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
10/17/05